

# **EXHIBIT D**

# **EXHIBIT C**

**to Ethicon's Response in Opposition to  
Plaintiffs' Motion to Exclude Dr. Larry T. Sirls'  
TVT/TVT-O General Opinions**

10 The deposition of LARRY T. SIRLS, II, M.D.,  
11 Taken at 41000 Woodward Avenue, Suite 200 East,  
12 Bloomfield Hills, Michigan,  
13 Commencing at 9:33 a.m.,  
14 Thursday, July 21, 2016,  
15 Before Cheryl McDowell, CSR-2662, RPR.

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<p>1            Doctor Sirls, who put together this      2        binder for you?</p> <p>3 A. That binder was put together by Butler Snow.</p> <p>4 Q. Okay. And who chose the articles that went in this      5        binder?</p> <p>6 A. I did.</p> <p>7 Q. Okay. And did you communicate to Butler Snow which      8        articles you wanted included here?</p> <p>9 A. Yeah. In my report we have these references, but      10      then there are additional references that are not in      11      my report that are in that folder.</p> <p>12 Q. Okay. Is everything that's in here reflected in      13      your reliance list?</p> <p>14 A. Yes.</p> <p>15 Q. Okay.</p> <p>16 A. It should be to the best of my knowledge, it should      17      be, yes.</p> <p>18 Q. And in the process of putting together your report      19      in this binder, did Butler Snow suggest or direct      20      you to any articles that they published for you to      21      look at or to include in this binder specifically?</p> <p>22 A. No.</p> <p>23 Q. Looking at Exhibits 4 and 5, those are internal      24      Ethicon documents.</p>	<p>1        number of peer-reviewed articles, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And you've published a number of peer-reviewed      4        articles on a wide variety of topics, correct?</p> <p>5 A. Mostly pelvic reconstructive surgery.</p> <p>6 Q. Okay. And lots of different subtopics, though,      7        within pelvic reconstructive surgery, correct?</p> <p>8 A. Yes.</p> <p>9 Q. And in publishing those articles and prior to      10      working as an expert for Ethicon, you've never      11      consulted internal industry or company documents for      12      any of the academic writings that you personally      13      have done, correct?</p> <p>14 A. Prior to receiving these documents, I had not      15      reviewed documents like this in my academic work.</p> <p>16 Q. Okay. And when were you provided with these      17      documents?</p> <p>18 A. I don't know exactly. Probably seven to nine months      19      ago.</p> <p>20 Q. Okay. And who selected these internal documents?</p> <p>21 A. Butler Snow.</p> <p>22 Q. Okay. And Butler Snow gave you a series it looks      23      like of about a hundred and fifty or so internal      24      Ethicon documents, give or take a few, is that</p>
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<p>1        Now, Doctor, you didn't have any access      2        to these documents prior to being retained by an      3        expert -- as an expert for Ethicon, correct?</p> <p>4 A. Yes, correct.</p> <p>5 Q. Okay. And these are documents that you reviewed in      6        connection with your expert report, correct?</p> <p>7 A. These are documents that I reviewed to make me      8        understand the process and understand what was going      9        on within the company.</p> <p>10      It is not part of my expert report. My      11      expert report is based on the literature.</p> <p>12 Q. Okay. And the types of documents that you've given      13      me in Exhibits 4 and 5, those are not the types of      14      documents that you would customarily rely on to do      15      your work in your peer-reviewed publications,      16      correct?</p> <p>17 A. These documents inform me, and I find them      18      interesting.</p> <p>19 Q. Okay.</p> <p>20 A. It is not something that I use for my report, for my      21      expert report.</p> <p>22 Q. Okay. So I'm asking you something that's a little      23      bit different.</p> <p>24      You as a clinician and academic publish a</p>	<p>1        correct?</p> <p>2 A. So some of these are internal documents. Some of      3        these are federal regulations. Some of these are      4        publications or abstracts or discussions. Some of      5        these are IFUs.</p> <p>6        So there are a variety of different      7        materials in those books.</p> <p>8 Q. Okay. I just want to make sure that I'm      9        conceptually getting that right.</p> <p>10      Would it be fair to say that what's in      11      Exhibit 8 which are the medical articles, those are      12      the medical articles that you personally selected as      13      reliance for your report, is that right?</p> <p>14 A. That's part of it, correct.</p> <p>15 Q. Okay. And then what is included in 4 and 5 are      16      things that the lawyers for Ethicon gave you to      17      review in connection with your expert report, is      18      that right?</p> <p>19 A. I want to clarify my earlier answer.</p> <p>20 Q. Sure.</p> <p>21 A. And that is that in this there are IFUs and things      22      that I had and was aware of and had read before they      23      were given to me.</p> <p>24 Q. Okay.</p>

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<p>1 specific last summer, fall, and one for a TVT-O      2 specific that we'll discuss today.      3 Is that the entire --      4 A. To the best of my knowledge, yes.      5 Q. Okay. And what did you do to prepare for your      6 deposition today?      7 A. I reviewed my materials, my report, the binders you      8 see in front of me, met with Mr. Koopmann.      9 Q. Okay. How many hours did you prepare for your      10 deposition?      11 A. For the deposition?      12 Q. Yes.      13 A. Well, I'm probably -- so does that include reviewing      14 all of this?      15 Q. Uh-huh.      16 A. Okay. Include writing up a report?      17 Q. No. Anything you've done specifically to prepare      18 for sitting here today and answering questions.      19 A. Would that include reviewing the documents for the      20 case, correct?      21 Q. Whatever you did.      22 A. So my report, I probably spent close to ninety hours      23 on my report.      24 Q. Okay.</p>	<p>1 Q. Okay. Now, you did a fellowship with Doctor Zimmern      2 in Los Angeles from 1992 to 1993, is that correct?      3 A. The lead, the lead physician in the fellowship was      4 Gary Leach. Phillippe Zimmern was an associate.      5 Q. Okay. And how closely did you work with      6 Doctor Zimmern at that time?      7 A. Very closely.      8 Q. Do you currently have a teaching appointment at any      9 educational institution?      10 A. I am the fellowship director at Beaumont Health for      11 female pelvic medicine and reconstructive surgery.      12 I direct urology research for the residency program      13 in the same institution. I'm a professor in urology      14 at Oakland University William Beaumont School of      15 Medicine.      16 Q. Okay. And do you currently act as a peer reviewer      17 for any medical journal?      18 A. Yes.      19 Q. And what medical journal is that?      20 A. The Journal of Urology, the Urology, Neurourology,      21 Urodynamics, Female Pelvic Medicine and      22 Reconstructive Surgery.      23 Q. Okay. Now, you offer your opinions in this case as      24 a clinician and a medical doctor, correct?</p>
<p>1 A. Reviewing additional documents, and I haven't      2 tallied up, so I'm giving you a generality.      3 Q. Sure.      4 A. I could be off a little bit. Reviewing the binders      5 that we see in front of us, the literature,      6 et cetera, another seventy hours or so. And then      7 the case-specific medical records, probably in the      8 thirties that I've done with that, and then I've met      9 with Mr. Koopmann probably somewhere between fifteen      10 and twenty hours.      11 Q. Okay. So if I'm doing my math right, it looks like      12 you spent anywhere between two hundred and five      13 to -- let's say two hundred to two hundred and ten      14 hours total drafting your report, doing the      15 case-specific report, reviewing your medical      16 records, and reviewing the documents for the      17 deposition, is that about right?      18 A. Somewhere in there.      19 Q. Okay. And we've had marked now the most current      20 copy of your CV.      21 And is this a complete and accurate      22 statement of your educational background and your      23 training?      24 A. Yes.</p>	<p>1 A. Clinician, medical doctor, academician.      2 Q. Okay. And it's based largely on your clinical      3 experience, correct?      4 A. Clinical experience, literature, discussions with      5 friends, colleagues, meetings, et cetera.      6 Q. And you're not holding yourself out as an expert      7 with regard to the material science of      8 polypropylene, correct?      9 A. I have done a lot of literature review on the      10 material science. It's very important in my      11 practice because I use these materials, and I would      12 say that I am a clinical expert in the use of these      13 materials, their outcomes, their complications,      14 et cetera.      15 Q. Okay. Now, you gave a deposition before, correct?      16 A. Yes.      17 Q. And have you reviewed that deposition in preparation      18 for your deposition here today?      19 A. No.      20 MS. FITZPATRICK: Okay. So why don't we      21 go ahead and mark this as Exhibit 9.      22 (Sirls TVT-9 marked and attached.)      23 BY MS. FITZPATRICK:      24 Q. Go ahead and take a look at that, Doctor. I'd like</p>

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<p>1 you to look at page forty-two, line seven through 2 ten.</p> <p>3 And you were asked at that time: You 4 don't hold yourself out as an expert with regard to 5 material science of polypropylene mesh, is that 6 correct? And you answered correct.</p> <p>7 Are you changing your testimony today?</p> <p>8 A. Yes, I am.</p> <p>9 Q. Okay. And tell me what you've done between December 10 12th, excuse me, December 14th, 2012, and today that 11 changed you from not being an expert about material 12 science with regard to polypropylene mesh and to now 13 holding yourself out as an expert on that specific 14 topic.</p> <p>15 A. So during this deposition, this one that we're 16 talking about, it's the first time I've been 17 involved in the process like this, and I was naive 18 and really did not understand the questions so well.</p> <p>19 In that time it's been three and a half 20 years. These products have come under much more 21 scrutiny, and I have gone to the literature, talked 22 to my friends, et cetera, gone to meetings, and have 23 become much more educated with regard to these 24 materials.</p>	<p>1 Q. Okay. But I'm not asking you whether you're an 2 expert in the use of the products and whether you're 3 an expert in the clinical outcomes and implanting 4 them in women.</p> <p>5 Maybe let me ask you this. How many 6 different kinds of polypropylene are there in the 7 world?</p> <p>8 A. So polypropylene is a polymer that I want to make 9 sure I understand your question.</p> <p>10 Do you mean how many makers are there?</p> <p>11 Q. How many different types?</p> <p>12 A. I don't understand your question.</p> <p>13 Q. Do you know that there's different grades of 14 polypropylene?</p> <p>15 A. What do you mean by different grades?</p> <p>16 Q. This is what I'm actually trying to get at. It 17 seems to me from your expert report that you are an 18 expert sitting here to tell me about the clinical 19 implications and uses of polypropylene mesh 20 products, particularly the TVT and the TTVT-O, in 21 women. That's what I got from your expert report, 22 okay?</p> <p>23 What I'm trying to get at is whether you 24 are also an expert on the chemical and physical</p>
<p>1 So I state that I am a clinical expert in 2 the use and clinical evaluation and outcomes of 3 these products.</p> <p>4 Q. Okay. Well, what I'm trying to get at is I 5 understand that you're here as a clinician to talk 6 about the use and the medical outcomes that come 7 with using specifically the TTVT and the TTVT-O 8 device, correct?</p> <p>9 A. Yes.</p> <p>10 Q. What I'm trying to get at is beyond that, those 11 clinical opinions that you hold and that you've 12 reported here, do you hold yourself out specifically 13 as someone who is an expert in the material of 14 polypropylene itself?</p> <p>15 A. I have reviewed thousands of pages of documents in 16 preparation, and I have reviewed quite a bit on 17 degradation, FDA regulations, preparation, 18 et cetera.</p> <p>19 I think that I probably know more about 20 the use of these products than many of the engineers 21 who write these reports because I'm the one who's 22 putting them in patients and evaluating their 23 outcomes. So, yeah, I feel I'm extremely well 24 versed and expert in using these products.</p>	<p>1 properties of polypropylene, polypropylene material 2 generally, not in a clinical setting, but just 3 there's people who specialize in polymers and 4 plastics.</p> <p>5 Are you one of those people?</p> <p>6 A. I don't specialize in polymers and plastics.</p> <p>7 Q. Okay.</p> <p>8 A. But I'm informed and educated about many of these 9 issues with polypropylene materials.</p> <p>10 Q. Okay. Great. Tell me about the different grades of 11 polypropylene.</p> <p>12 A. What I can tell you is that prolene mesh is 13 different than polypropylene because it's treated, 14 right, with antioxidants.</p> <p>15 Q. And what are those antioxidants?</p> <p>16 A. Santanox and DTL-DP.</p> <p>17 Q. And tell me how a manufacturer decides what 18 concentration of antioxidants should be used in a 19 particular polypropylene product.</p> <p>20 A. I don't know that.</p> <p>21 Q. Okay. Tell me the difference between the 22 polypropylene that is used for an Ethicon product 23 versus a polypropylene that is used for a Boston 24 Scientific product.</p>

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<p>1 A. Our hospital has a policy on all material explants, 2 and it goes to the pathology lab and we get a 3 pathology report. They do not study the 4 polypropylene for degradation.</p> <p>5 Q. Okay. So in your clinical practice, you don't have 6 any experience in reviewing pathology or looking at 7 pathology microscopically for degradation, is that 8 right?</p> <p>9 A. I have not done it in my clinical practice on 10 materials that I've explanted.</p> <p>11 Q. Okay. Have you done it in another way in your 12 clinical practice?</p> <p>13 A. Clinical practice to me means reading the literature 14 and understanding things. So it's just in the 15 literature and discussions. That's where my 16 information's coming from.</p> <p>17 Q. Maybe this is where we're talking a little past each 18 other. Just by way of shorthand, when I talk about 19 your clinical practice, I'm talking about your 20 actual treatment of women, okay? When we talk about 21 your academic practice, I'm talking about your 22 knowledge of the literature and the articles you 23 write and all of that type of stuff. So I want to 24 focus solely on your clinical practice.</p>	<p>1 clinical experience because they're logical to us, 2 they're intuitive, and we think that it may be an 3 upgrade over what we're doing.</p> <p>4 For example, I'm starting a study next 5 month where I'll be implanting a device that's never 6 been done before like this, and I'll be the first 7 one doing it. There's no data on that.</p> <p>8 Q. Okay. Is that part of a clinical trial?</p> <p>9 A. In that case it will be.</p> <p>10 Q. Okay. And that's a case where you tell the women or 11 men who are getting this new device that they are 12 part of a clinical trial, correct?</p> <p>13 A. That is correct.</p> <p>14 Q. And you'll tell them that they are getting a device 15 that doesn't have an established record of safety, 16 correct?</p> <p>17 A. That's correct.</p> <p>18 Q. And you'll tell them they are getting a device that 19 doesn't have an established record of efficacy, 20 correct?</p> <p>21 A. So let me also back up to your prior question on 22 safety. When we do these, we have typically very 23 similar things that have been done that have been 24 shown to be safe and effective. So we're not going</p>
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<p>1 There's nothing in your clinical practice 2 of treating women where you've done anything to 3 specifically look for or study degradation of 4 polypropylene mesh explants, correct?</p> <p>5 A. Correct.</p> <p>6 Q. And so your knowledge comes from reading somebody 7 else's articles in the medical and scientific 8 literature, is that right?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. You started using the TVT device in 2005, 11 correct?</p> <p>12 A. Yeah. It may have been 2004. I'm sorry. It's in 13 that time period.</p> <p>14 Q. Okay. And prior to using a new medical device, you 15 personally as a physician would want to be convinced 16 that the device was safe and effective, correct?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And you wouldn't use personally a medical 19 device that didn't have a proven track record of 20 safety?</p> <p>21 A. Well, so that's where surgery is a little bit 22 different than, for example, medications that can be 23 powered and randomized in large studies. In surgery 24 we will often do procedures that do not have a large</p>	<p>1 in and doing something that we don't have a concept 2 of safety and efficacy for.</p> <p>3 Similarly, when we do surgical implants, 4 from my first TVT or my first TOT, they were not in 5 a clinical trial, and I had to tell my patient, 6 look, this is my first one, but this is why I'm 7 doing this, it's logical.</p> <p>8 Q. And so with your first TVT and TVT-O that you did, 9 prior to implanting those devices, did you do a 10 review of the medical and scientific literature to 11 satisfy yourself that the procedures and the devices 12 were safe?</p> <p>13 A. Yeah, that's a really good question because, as you 14 know, the procedures were developed in '96, '97, 15 '98, and I did not put my first one until 2004, 16 2005. So I was very cautious and I waited and 17 watched the literature.</p> <p>18 We're talking about TVT, right?</p> <p>19 Q. Yes.</p> <p>20 A. TOT was later, 2001, 2002, 2003. So, you know, I 21 was very cautious and watched the literature. So I 22 did do that exactly before, before I implanted it in 23 my first clinical patient, and I was very 24 comfortable.</p>

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<p>1 Q. Okay. So it was important to you that you had      2 scientific data before implanting the TVT device      3 into women, correct?</p> <p>4 A. Again, there are different degrees of comfort and      5 different amounts of data that are necessary before      6 a surgeon feels comfortable doing something.</p> <p>7         But, yeah, typically before I'm going to      8 do it on my patient, I will have some literature,      9 some discussions, some meetings, some information      10 that makes me feel comfortable moving ahead.</p> <p>11 Q. And you did that with the TVT device, right?</p> <p>12 A. I did.</p> <p>13 Q. And you did that with the TVT-O device, right?</p> <p>14 A. I did.</p> <p>15 Q. What literature did you rely on to satisfy yourself      16 that the TVT was safe before you started using it?</p> <p>17 A. The literature that would have been published at      18 that time. I don't recall what was published at      19 that time in that time period. I was watching very      20 actively because I was skeptical, I was very      21 skeptical.</p> <p>22         But, let's see. It was Nilsson, Ulmsten,      23 and then the people in the states. Who were the      24 early TVT people? Maybe Dennis Miller, maybe Vince</p>	<p>1 prior to implanting your first TVT?</p> <p>2 A. So what the information I probably would have      3 received from Ethicon at that time would have been      4 probably a booklet or a slide deck on the procedure.      5 Of course, there's the IFU.</p> <p>6         And primarily it's the literature, my      7 friends. I don't rely as much on slide decks, IFUs,      8 as I do on these other sources of information.</p> <p>9 Q. Okay. But you do look at the information, I think      10 you previously testified that you look at the      11 information the medical device manufacturer would      12 give you prior to implanting their product, correct?</p> <p>13 A. Yeah. It may not be important to me, but, yeah, I      14 look at it.</p> <p>15 Q. And you would expect that Ethicon would fully      16 disclose to you all of the risks that it knew of, it      17 knew were associated with the TVT product, correct?</p> <p>18 MR. KOOPMANN: Object to form.</p> <p>19 THE WITNESS: As a surgeon who had done,      20 I don't know, a thousand slings before I did my      21 first TVT, I really don't need Ethicon telling me      22 the risks and complications of sling procedures.      23 They would have to tell me something that would not      24 commonly be known to me.</p>
<p>1 Lucente. I don't recall who were the major      2 publishers in that time period.</p> <p>3         Also at the meetings, the meetings are      4 very important for us. People come up, they give      5 their presentation, we're able to talk informally,      6 and that helps me quite a bit.</p> <p>7 Q. Okay. And did you receive information from Ethicon      8 prior to using the TVT?</p> <p>9 A. So what I would have done is I would have had to had      10 some training by Ethicon and/or some mentoring by      11 Ethicon before doing that. I would have gone to a      12 cadaver lab or would have gone to a surgeon's home      13 site and observed or done both.</p> <p>14         I apologize. I don't recall because it's      15 just been so long ago. But I recall doing all of      16 these things, cadaver labs, visiting surgeons,      17 watching them do them.</p> <p>18         I had done a lot of surgeries, so I was      19 pretty comfortable with these techniques. We use      20 trocars all the time when we do slings and other      21 things.</p> <p>22 Q. I'm asking you specifically, though, about Ethicon.</p> <p>23 A. Okay.</p> <p>24 Q. Okay. What information did you receive from Ethicon</p>	<p>1 BY MS. FITZPATRICK:</p> <p>2 Q. So a medical device -- so your testimony is a      3 medical device manufacturer does not have a      4 responsibility to tell physicians who are using its      5 product of the risks it knows are associated with      6 the product, is that what you're saying? There's no      7 obligation to do that?</p> <p>8 MR. KOOPMANN: Object to form.</p> <p>9 BY MS. FITZPATRICK:</p> <p>10 Q. I mean, they either have to tell you or they don't.      11 I just want to know which one you think it is.</p> <p>12 A. I think that they should tell us risks that would      13 not commonly be known to surgeons and that would be      14 unique to their device.</p> <p>15 Q. And you realize, Doctor, that not everybody who's      16 used a TVT has the same level of experience      17 implanting a thousand slings before they started      18 using a TVT device, correct?</p> <p>19 A. Probably.</p> <p>20 Q. And not every physician has the opportunity that you      21 do to go to all of these meetings and to meet with      22 all of your colleagues, correct?</p> <p>23 A. I'm not sure. Probably.</p> <p>24 Q. Okay. And you realize that where you practice and</p>

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<p>1 the mid-urethral sling which is why the whole world      2 went to mid-urethral slings.</p> <p>3 Q. Your hands are not everybody's hands, though,      4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. And you recognize there are reported complications      7 that are unique to mesh slings that are not reported      8 in association with fascial slings, correct?</p> <p>9 A. Those complications in my mind would be entirely      10 mesh related --</p> <p>11 Q. Okay.</p> <p>12 A. -- and nothing else.</p> <p>13 Q. And nobody -- not everybody has the same results      14 with polypropylene mid-urethral slings that you      15 have, correct?</p> <p>16 A. Interestingly, as I look at the meta-analyses, the      17 data that I see is pretty consistent with my      18 experience.</p> <p>19 Q. Okay. So you're pretty middle of the road, you get      20 the same results that other people do, is that      21 right?</p> <p>22 A. Yeah. I would say that my results are similar to      23 what we see in the very large studies.</p> <p>24 Q. Okay.</p>	<p>1 you do a year?</p> <p>2 A. I'm not sure. A hundred. I don't know. Two      3 hundred. I'm not sure.</p> <p>4 Q. Okay. Let's try to just break it down. How many      5 roughly percentage-wise if you can give me, how many      6 of the slings that you implant are the Abbrevo?</p> <p>7 A. So my obturator approach, it's about ninety percent      8 of what I do.</p> <p>9 Q. Okay. And about how many are the retropubic?</p> <p>10 A. The remaining. Well, maybe nine percent to probably      11 one percent, maybe two percent fascial slings at      12 this time.</p> <p>13 Q. Okay. And you agree with me the fascial sling is      14 within the standard of care even though it's not      15 your preferred surgical intervention, correct?</p> <p>16 A. Yes.</p> <p>17 Q. All right. So you offered a report on the TTVT-O      18 specifically.</p> <p>19 What are the differences between the      20 TTVT-O and the Abbrevo product that you use?</p> <p>21 A. So, first of all, let me just qualify that. In our      22 field we tend to -- TTVT-O has become kind of a very      23 generic term. So sometimes I'll say TTVT-O and what      24 I mean is obturator sling.</p>
<p style="text-align: center;">Page 55</p> <p>1 A. Some, you know, some differences, but --</p> <p>2 Q. Well, we will -- I want to look at some of those in      3 a little bit.</p> <p>4 A. Okay.</p> <p>5 Q. But before we get there, so you do fascial slings.      6 What retropubic slings do you use?</p> <p>7 A. I use the TTVT Exact.</p> <p>8 Q. And what obturator slings do you use?</p> <p>9 A. I use the Abbrevo.</p> <p>10 Q. And the Abbrevo is a different or a modified version      11 of the TTVT-O, is that right?</p> <p>12 A. I look at the Abbrevo as an upgraded product. When      13 you come out, when you have experience and you have      14 time to reflect and think about the technologies,      15 the next generation is often slightly improved over      16 the first. So --</p> <p>17 Q. Is the Abbrevo an updated improvement over the      18 traditional TTVT-O in your opinion?</p> <p>19 A. I like the Abbrevo. It's my sling of choice now for      20 many, many reasons. In fact, it's my primary sling      21 of choice. I prefer that over retropubic slings.</p> <p>22 But if the Abbrevo were off the market      23 tomorrow and all we had was TTVT-O, I would use that.</p> <p>24 Q. Okay. Well, let's say how many sling surgeries do</p>	<p style="text-align: center;">Page 57</p> <p>1 Q. Okay.</p> <p>2 A. Okay. Just to qualify that.</p> <p>3 Q. Okay. That's fair enough.</p> <p>4 I want to talk very specifically about      5 not TOT, not the transobturator slings generally but      6 the Ethicon TTVT-O device.</p> <p>7 A. Okay.</p> <p>8 Q. Okay. So the difference between the Ethicon TTVT-O      9 device and the Ethicon Abbrevo device.</p> <p>10 A. Yes.</p> <p>11 Q. What are the differences?</p> <p>12 A. The differences are first that the Abbrevos or      13 Abbrevos are all laser-cut mesh.</p> <p>14 That's not as important to me clinically.</p> <p>15 The most important thing to me clinically is it's a      16 shorter length.</p> <p>17 Q. And having a shorter length, it doesn't go as far      18 out into the groin and thigh, correct, as the      19 traditional TTVT-O?</p> <p>20 A. Correct.</p> <p>21 Q. Okay. And what in your opinion is the advantage of      22 having the shorter length of the Abbrevo versus the      23 TTVT-O?</p> <p>24 A. That's actually a really important issue, and the</p>

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<p>1 concern is groin pain, and clinically, I see this      2 very infrequently but I still worry about it because      3 this is a quality of life procedure, and I'm trying      4 to make sure my patients are happy when we're done.      5         And although I see, again, I would say      6 extremely infrequent groin pain that lasts more than      7 a few weeks, if I can try and minimize that by      8 having a mesh band that does not go through the      9 adductor muscle group, then that's intuitive to me.</p> <p>10 Q. Do you believe that the -- so your primary reason is      11 you believe that there's a decrease in the chance of      12 a long-term groin pain in a woman.</p> <p>13         Is that sort of my layperson's      14 interpretation of what you're saying?</p> <p>15 A. So it was really an intellectual decision because      16 clinically I was not seeing problems with groin      17 pain. I mean, it was very, very infrequent. We      18 talk about it in the literature, we see it in      19 conferences, and it had my attention. The numbers      20 are very low, but I worry about it. You worry.      21 That's what I do.</p> <p>22         So when the shorter mesh came out, I      23 looked at it, I said this is logical. Maybe if I      24 have one patient in a thousand who has that</p>	<p>1 stress incontinence, and if that's the case, those      2 are the three procedures we discuss.</p> <p>3 Q. Okay. And why do you use the TTVT Exact over just      4 the TTVT-O?</p> <p>5 A. There's two scenarios where I might do that. Number      6 one is if the patient has had a prior mid-urethral      7 sling, there's some data, not great data, but      8 there's some data that argues that a retropubic      9 vector improves overcomes over the obturator vector      10 in that specific subgroup.</p> <p>11         The second reason would be if the patient      12 has dyspareunia or pelvic pain, and what I would do      13 in that patient is on exam, I would feel their      14 pelvic floor muscles, and if they have any evidence      15 of pelvic floor muscle pain or discomfort, I would      16 not use an obturator sling in that patient.</p> <p>17 Q. Okay. I think I misspoke. I was going to ask you      18 that question too, so you already gave me that.</p> <p>19         Why would you use a TTVT Exact over the      20 TTVT-R?</p> <p>21 A. I thought you said TTVT-O.</p> <p>22 Q. I apparently did. I just misspoke.</p> <p>23 A. Okay.</p> <p>24 Q. So --</p>
<p style="text-align: center;">Page 59</p> <p>1 complication and I can prevent that one patient in a      2 thousand from having it, I'd like to do that.</p> <p>3 Q. Okay. And is there anything else that recommends      4 the Abbrevio over the TTVT-O device to you?</p> <p>5 A. No.</p> <p>6 Q. Okay. Do you even implant the TTVT-O at all, or do      7 you just use the Abbrevio at this point?</p> <p>8 A. At this point I use the Abbrevio. If we don't have      9 it, I'll use a TTVT-O.</p> <p>10 Q. Okay. And when did you change from the TTVT-O to the      11 Abbrevio?</p> <p>12 A. I'm sorry. I'm not sure. A few years ago, a couple      13 few years ago.</p> <p>14 Q. Okay. Now, so a woman comes in to see you and she      15 needs a surgical intervention for stress urinary      16 incontinence. You offer her three potential      17 procedures, the Abbrevio, the TTVT Exact, and the      18 fascial sling.</p> <p>19         Those are your three options, is that      20 right?</p> <p>21 A. Well, there's another surgical option that's      22 periurethral injection.</p> <p>23         But we're -- I'm assuming that we're      24 talking about a patient with simple, straightforward</p>	<p style="text-align: center;">Page 61</p> <p>1 A. TTVT-R. I like the curve of the trocar and the hand      2 movement, but that's personal preference. I've used      3 them both.</p> <p>4         Some people really like the big trocar.</p> <p>5 They feel they can guide it easier and have more      6 control over it. I happen to like the other trocar.      7 It's just personal preference.</p> <p>8 Q. Okay. And so let's go back to the question that I      9 asked and you answered. The primary reason -- I      10 just want to get this in my mind. A woman comes in      11 to you for a surgical intervention, okay?</p> <p>12         Is your -- generally your first      13 recommendation that they have the Abbrevio sling, and      14 you only go to the TTVT Exact or the fascial sling if      15 there's some kind of reason why you don't think that      16 the Abbrevio is particularly suited for that woman,      17 is that right?</p> <p>18 A. Yeah. There are a few things that I look at, but if      19 there are none of the risk factors that I am      20 considering, my first choice is an inside-out      21 obturator sling which is the Abbrevio.</p> <p>22 Q. Okay. And the risk factors that you discussed were      23 women who already have some type of pelvic floor or      24 pelvic muscle discomfort or dyspareunia, is that</p>

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<p>1 right?</p> <p>2 A. Yes.</p> <p>3 Q. And is there any other risk factor that you can</p> <p>4 identify for me that would have you recommend the</p> <p>5 Exact over the Abbrevio?</p> <p>6 A. Yes. That is in a patient who will have had prior</p> <p>7 mid-urethral sling, and those patients, again,</p> <p>8 there's some literature, mostly case series and</p> <p>9 things, not great, no Level I evidence, that argues</p> <p>10 that the retropubic vector in those patients may be</p> <p>11 better than the obturator vector, but studies like</p> <p>12 that, you know, that are not large they've been</p> <p>13 proven wrong before.</p> <p>14 For example, you know, when we looked at</p> <p>15 the retropubic versus the obturator sling, one of</p> <p>16 the big issues was if a patient has ISD, if they</p> <p>17 have severe leakage, is the retropubic sling tighter</p> <p>18 or not than the obturator, and I have to say I</p> <p>19 thought that it was, and I was in a group that</p> <p>20 thought that it was. There's papers that said it</p> <p>21 was, some papers said that it wasn't.</p> <p>22 So when we did our large six hundred</p> <p>23 patient prospective randomized trial and then we</p> <p>24 evaluated those patients according to leak point</p>	<p>1 A. Nothing that I can think of right now.</p> <p>2 Q. Okay. And then you also do a very small number of</p> <p>3 fascial slings, is that correct?</p> <p>4 A. Yes.</p> <p>5 Q. Are those ever -- do you ever recommend a fascial</p> <p>6 sling to a patient?</p> <p>7 A. I do.</p> <p>8 Q. Okay. And in what candidates would you recommend a</p> <p>9 fascial sling or a polypropylene mid-urethral sling?</p> <p>10 A. So the brilliant thing about the mid-urethral sling</p> <p>11 is that it's tension free. That was just a critical</p> <p>12 advance, and it's changed. It's been the single</p> <p>13 most important thing that has improved the side</p> <p>14 effect profile of these procedures.</p> <p>15 The fascial slings are placed at the</p> <p>16 bladder neck, not the mid-urethra, and historically</p> <p>17 they have been what we call compressive and which</p> <p>18 means obstructive which means that the patients have</p> <p>19 higher urgency rates and higher UTI rates, all of</p> <p>20 which are proven in the literature.</p> <p>21 So when I have a patient whose urethra is</p> <p>22 mobile, it's moving, then I can put a mid-urethral</p> <p>23 sling in them. The urethra moves, hits the sling,</p> <p>24 and it works. Dynamic kinking is what we would call</p>
<p>1 pressures which is a severity of urethral</p> <p>2 dysfunction, we found that both slings worked</p> <p>3 exactly the same.</p> <p>4 So that was the first really big study to</p> <p>5 inform us as a field that the obturator sling works</p> <p>6 as well as the retropubic sling in patients with</p> <p>7 severe dysfunction, so that's not something that I</p> <p>8 use.</p> <p>9 Interestingly, when I go to the meetings,</p> <p>10 everybody at the meetings will say retropubic slings</p> <p>11 are tighter, and that's because they're not reading</p> <p>12 the literature.</p> <p>13 Q. Okay. So I want to go back to my question.</p> <p>14 Dyspareunia, pelvic floor muscle dysfunction, that's</p> <p>15 one risk factor that would have you recommend the</p> <p>16 TVT-R to a small subgroup of your -- subpopulation</p> <p>17 of your patients, right?</p> <p>18 A. So the retropubic sling instead of an obturator?</p> <p>19 Q. Right. Prior mid-urethral sling, you would go to a</p> <p>20 retropubic over the obturator in that case, correct?</p> <p>21 A. For now until that's proven to be wrong.</p> <p>22 Q. Okay. Anything else, any other risk factors that</p> <p>23 would have you recommend to a woman that she have a</p> <p>24 retropubic as opposed to an Abbrevio device?</p>	<p>1 that in the literature.</p> <p>2 But when a patient is scarred and the</p> <p>3 urethra is not moving, then I have to take my sling</p> <p>4 and I have to take my sling to the urethra and</p> <p>5 compress it, and that, I'm going to place fascia</p> <p>6 because we don't put mesh under tension. Mesh under</p> <p>7 tension could erode into the urethra.</p> <p>8 So a fascial sling is typically under a</p> <p>9 little bit more compression, and what we know is</p> <p>10 commonly we're obstructing these patients which</p> <p>11 leads, again, to a whole another set of side effects</p> <p>12 which sometimes for a patient is more bothersome</p> <p>13 than their leakage in the first place. So it gets</p> <p>14 to be a very tricky, tricky population.</p> <p>15 Q. Okay. Now, regardless of what procedure you're</p> <p>16 doing, the Abbrevio, the TVT Exact, or the fascial</p> <p>17 sling, you discuss the options with your patients,</p> <p>18 correct?</p> <p>19 A. Yes.</p> <p>20 Q. And you give them informed consent, correct?</p> <p>21 A. Yes.</p> <p>22 Q. And what -- let's start with the Abbrevio. What are</p> <p>23 the risks that you tell your patients about that can</p> <p>24 be associated with the use of the Abbrevio device?</p>

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<p>1 That is unique to this.</p> <p>2 Prolene may potentiate existing</p> <p>3 infection. The next one's on obstruction. We know</p> <p>4 that. Acute or chronic pain, any surgery we do can</p> <p>5 do that. Voiding dysfunction, that goes up with the</p> <p>6 bullet above. I don't know why they split that into</p> <p>7 two different bullets. Pain with intercourse, we</p> <p>8 know about that. Neuromuscular problems, again,</p> <p>9 same idea. We know about that. Recurrence,</p> <p>10 bleeding, revisions, and then the last one, a</p> <p>11 permanent implant that integrates into the tissue.</p> <p>12 So that is unique to this when they talk about mesh.</p> <p>13 However, if I have to go in and take the</p> <p>14 Burch sutures out that eroded into a bladder or</p> <p>15 fascial sling is out that is obstructing, that can</p> <p>16 be a very difficult dissection as well.</p> <p>17 Q. Let me ask you based on these adverse reactions that</p> <p>18 you just reviewed, is there any reason that you know</p> <p>19 of from your medical and clinical point of view, any</p> <p>20 reason that those adverse reactions that are</p> <p>21 identified in the post 2015 IFU could not have been</p> <p>22 included in the pre-2015 IFU?</p> <p>23 MR. KOOPMANN: Object to form,</p> <p>24 foundation.</p>	<p>1 BY MS. FITZPATRICK:</p> <p>2 Q. I'm not asking you that. I'm asking, you are a</p> <p>3 clinician and a medical doctor.</p> <p>4 A. Yeah.</p> <p>5 Q. I'm not asking you -- there's no way you can know</p> <p>6 what Ethicon was thinking.</p> <p>7 A. Right.</p> <p>8 Q. I'm asking from a purely medical point of view, what</p> <p>9 was known in the medical community about potential</p> <p>10 adverse reactions to the TTV device. Is there any</p> <p>11 reason based on that body of knowledge that you have</p> <p>12 that any of these adverse reactions could not have</p> <p>13 been identified in an IFU prior to 2015?</p> <p>14 A. So, I apologize, but, you know, your question could</p> <p>15 not have -- I'm getting thrown off by that.</p> <p>16 Q. Is there anything new here that physicians didn't</p> <p>17 know prior to 2015?</p> <p>18 A. No. In fact, I would argue that we could probably</p> <p>19 still have the same four bullet points here, and I</p> <p>20 would still be comfortable with that.</p> <p>21 Q. Or we could also argue that each of these adverse</p> <p>22 reactions could have made it into the earlier IFU</p> <p>23 because they were known as potential complications</p> <p>24 and adverse events with the TTV, right? It could</p>
<p>1 THE WITNESS: So my understanding when</p> <p>2 you look at both federal regulations and guidelines</p> <p>3 on IFUs, it has to be something that is unique, that</p> <p>4 is unique to the procedure and not commonly known.</p> <p>5 And that's kind of where the whole</p> <p>6 argument is here is that these things are commonly</p> <p>7 known. The only thing that is unique here are the</p> <p>8 ones that specifically deal with mesh. We know</p> <p>9 removing it's hard, but mesh exposure is unique to</p> <p>10 these products, yes.</p> <p>11 BY MS. FITZPATRICK:</p> <p>12 Q. It's not my question.</p> <p>13 A. I'm sorry.</p> <p>14 Q. Is there any reason based on your medical</p> <p>15 knowledge and your clinical knowledge, is there</p> <p>16 any reason why any or all of these adverse</p> <p>17 reactions that are identified in the 2015 IFU</p> <p>18 could not have been listed in the pre-2015 IFU?</p> <p>19 Are these new things that people didn't know about</p> <p>20 until 2015?</p> <p>21 MR. KOOPMANN: Object to form.</p> <p>22 THE WITNESS: So I can't really comment</p> <p>23 on what the people at Ethicon were thinking when</p> <p>24 they --</p>	<p>1 have gone either way?</p> <p>2 A. But this is just, I mean, I don't know who selected</p> <p>3 these things. We don't have blood clot on here. We</p> <p>4 could have gotten into blood clot.</p> <p>5 Q. We could go down to the other adverse reactions as</p> <p>6 well.</p> <p>7 A. Yeah.</p> <p>8 Q. I'm just asking you, Doctor, I don't care which IFU</p> <p>9 you like better.</p> <p>10 A. Okay.</p> <p>11 Q. I'm just asking you, is there any reason that you</p> <p>12 know of based on your knowledge of the medical and</p> <p>13 scientific literature that what Ethicon chose to put</p> <p>14 into its IFU in 2015 could not have been</p> <p>15 incorporated into an earlier version of the IFU</p> <p>16 based on medical and scientific knowledge? That's</p> <p>17 all.</p> <p>18 A. You know, it's the could not. It's like a double</p> <p>19 negative.</p> <p>20 So, so are you saying that Ethicon could</p> <p>21 have put these in earlier IFUs, is that a simpler</p> <p>22 way of saying it?</p> <p>23 Q. Could Ethicon have put these adverse events into</p> <p>24 early IFUs?</p>

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1 weight? Do you recall that?	1 TVT-O devices was safe and effective when you
2 A. So there's the Amid study which is the original	2 started using the TVT-O?
3 study on pore size, Type I, Type II, Type III, Type	3 A. Yeah. So when the TVT-O came out, the idea was that
4 IV.	4 it's the exact same mesh, it's the exact same
5 I also looked at Pam Moalli's paper from	5 location, it's just a different way of getting it
6 2008 --	6 there, and we were very comfortable with that.
7 Q. And is it your --	7 Q. Do you offer the Burch procedure as a stress urinary
8 A. -- and many other articles and documents looking at	8 incontinence treatment to your patients today?
9 pore size.	9 A. I do not.
10 Q. That Moalli paper that you just referenced, that	10 Q. Why not?
11 contains a table in it that lists the density and	11 A. So we did a large prospective randomized trial on
12 pore size of various incontinence slings?	12 Burch, and it just, it's not, it's not durable.
13 A. Yes.	13 It's not effective. So when I would do it before,
14 Q. And that's something you've reviewed?	14 it was only when we were in the abdomen, and it was
15 A. Yes.	15 there, it was easy, we were in the abdomen, we would
16 Q. You testified earlier today that you've explanted	16 do a Burch.
17 some polypropylene mesh slings or portions of some	17 But now when they're in the abdomen, if
18 polypropylene mesh slings, is that right?	18 they need an anti-incontinence procedure, I'd do a
19 A. That's correct.	19 mid-urethral sling. So I'll let them finish in the
20 Q. And when you had occasion to do that, did you look	20 belly, close, then I'll go vaginally and I will do
21 at the mesh that you explanted?	21 mid-urethral sling because they're more effective,
22 A. Yes.	22 and I think that they have a better safety profile.
23 Q. In that gross examination of the mesh, did you	23 Q. Have you actually seen lower rates of groin pain or
24 observe any degradation?	24 leg pain with your TVT Abbrevo patients than you did
Page 127	Page 129
1 A. It looked normal to me.	1 with your TVT-O patients?
2 Q. And does your outcomes with your patients in whom	2 A. No. I really haven't. I haven't formally studied
3 you've implanted a mid-urethral polypropylene sling	3 it, but anecdotally in my, just evaluation of my
4 like the TTV or TVT-O inform your opinion about	4 patients, I have not seen that. We do look at these
5 whether or not the mesh in those slings degrades?	5 patients when we do our trials.
6 A. Yeah. I find it just, I find it so interesting to	6 I don't have a prospective sling database
7 read these internal documents on mesh degradation	7 but I have retrospective sling databases, and we
8 because it was a surprise to me and because	8 have not seen a difference.
9 clinically I just have not seen any evidence of this	9 Q. Does the TVT Abbrevo use the exact same mesh as the
10 at all.	10 TVT-O?
11 We have long-term studies looking at	11 A. No. The Abbrevo is a laser-cut mesh.
12 patients looking at their clinical outcome, clinical	12 Q. But apart from the cutting technique, is it the same
13 outcome meaning continued improvement in symptoms	13 mesh?
14 but also meaning lack of progression of scar tissue,	14 A. Yes, it's the same mesh.
15 pain, discomfort, et cetera. So I just don't see	15 Q. And there's laser-cut TVT-O mesh, correct?
16 any clinical evidence that this is an issue.	16 A. There is, that's correct.
17 Q. There was some discussion earlier about what	17 Q. In addition to mechanically cut TVT-O devices?
18 literature you relied on at the time that you	18 A. That's correct.
19 started to use the TTV and at the time that you	19 Q. But the mesh in the TVT Abbrevo and the TVT-O is the
20 started to use the TVT-O.	20 same polypropylene?
21 Do you recall that generally?	21 A. Yes, it's the same weave, monofilament.
22 A. Yes, yes.	22 Q. It's the same weight or density?
23 Q. Did you also rely on the TTV literature that existed	23 A. Same weight, same pore size. It's a hundred grams
24 as something that made you feel comfortable that the	24 per liter squared.

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<p>1 Q. Does the mesh used in the two devices lay under the 2 urethra at the same spot? 3 A. It does. We do that on purpose. 4 Q. Does the TVT Exact use the exact same mesh as the 5 TVT with the exception of the cutting technique? 6 A. Yes, yes, it is. 7 Q. But, again, with the TVT there's also laser-cut mesh 8 available, is that your understanding? 9 A. That's correct. 10 Q. And is the TVT Exact mesh the same weight and pore 11 size as the TVT mechanically cut mesh? 12 A. Yes, it is. 13 Q. And that mesh lays under the urethra at the same 14 place? 15 A. Yes. 16 Q. I'm going to ask you a couple of follow-up questions 17 about Exhibit 11 and 12. 11 is the TVT IFU before 18 2015, and 12 is the TVT IFU before 2015. 19 A. Okay. I have them both. 20 Q. Which one do you have in front of you right now that 21 you're looking at? 22 A. I have the TVT-O one. 23 Q. Okay. So if you look at the TVT-O marked as 24 Exhibit 12, there was some discussion earlier about</p>	<p>1 However, I did not review that carefully 2 enough before talking about that this morning, and 3 it does clearly say that. 4 BY MR. KOOPMANN: 5 Q. And the TVT-O IFU on the first page, one of the 6 things it says in a paragraph at the top of the 7 first substantive page I'll call it that says 8 English at the top, it says: The device should be 9 used only by physicians trained in the surgical 10 treatment of stress urinary incontinence and 11 specifically in implanting the Gynecare TVT 12 obturator device, is that correct? 13 A. Yes, that's correct. 14 Q. And if you go to the TVT IFU marked as Exhibit 11, 15 it also says: The device should be used only by 16 physicians trained in the surgical treatment of 17 stress urinary incontinence and specifically in 18 implanting the Gynecare TVT device, is that correct? 19 A. Yes, that's correct. And really, all these 20 decisions are not -- these decisions are all made by 21 the local hospitals, universities, et cetera, who do 22 privileging, chairman of the department. That's how 23 we decide who can implant and who cannot implant. 24 It's a local decision made by the administrations</p>
<p style="text-align: center;">Page 131</p> <p>1 the adverse reaction section. 2 Do you recall that? 3 A. Yes. 4 Q. Right above the adverse reaction section, there's a 5 section that says warnings and precautions, is that 6 right? 7 A. Yes. 8 Q. And if you look at the fifth bullet point from the 9 bottom of that list of warnings and precautions, it 10 says: Transient leg pain lasting twenty-four to 11 forty-eight hours may occur and can usually be 12 managed with mild analgesics, is that correct? 13 A. Correct, yes. 14 Q. And then if you look at the Exhibit 11 which is the 15 TVT IFU, before 2015, you don't see that same 16 notation of transient leg pain, do you? 17 A. That's correct. 18 Q. So in that respect, would you agree that these TVT 19 and TVT-O IFUs before 2015 do set forth a different 20 risk profile? 21 MS. FITZPATRICK: Objection. 22 THE WITNESS: Yeah. I apologize for 23 that. I will tell you that the print is so small, I 24 can hardly see it even with my glasses on.</p>	<p style="text-align: center;">Page 133</p> <p>1 and departments at the local hospitals. 2 Q. Is the fact that data can change over time one of 3 the reasons surgeons continue to do studies and 4 systematic reviews and meta-analyses? 5 A. Yeah, and I alluded to that in talking about how the 6 literature develops, and we learn more and more 7 things as time goes on. 8 Q. And is a continuing review of the literature 9 something that surgeons do as part of their 10 practice? 11 A. It's what we constantly do. In fact, in programs 12 like ours, we have a journal club every month 13 specifically to look at the new literature to keep 14 ourselves updated. 15 Q. Can a risk profile of a device change over time? 16 A. Absolutely, especially as we learn more about it and 17 we're informed. 18 Q. The additional adverse reactions and other adverse 19 reactions that counsel went over earlier with you in 20 the 2015 IFUs for the TVT and TVT-O which have been 21 marked as Exhibits 13 and 14 respectively, in your 22 opinion was there any reason that those additional 23 adverse reactions that were not seen in prior 24 versions of the IFU needed to be included in the</p>

1 products versus AMS products, and what you told me, 2 I did not do one at my institution but I 3 participated in the overall study. 4 A. Yeah. So, so we did not do it at Beaumont, you're 5 right. I participated in the study that pulled the 6 data and looked at it on the national level. 7 Q. Those weren't your patients, right? 8 A. Some of them were but not all of them, no. 9 Q. You didn't do it at Beaumont? 10 A. We did not do a study at Beaumont where we compared 11 Ethicon versus AMS or somebody else. 12 Q. And those are your patients who you haven't done a 13 study in your patients at Beaumont that compared 14 Ethicon to another manufacturer, right? 15 A. But what we did is we participated in the study that 16 compared AMS and Ethicon on a national level. 17 Q. Okay. 18 A. But not on a local level. 19 MS. FITZPATRICK: That's all that I have. 20 Thank you. 21 22 (Deposition concluded at 12:50 p.m.) 23 24	Page 158
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1 STATE OF MICHIGAN ) 2 COUNTY OF LIVINGSTON ) 3 CERTIFICATE OF NOTARY PUBLIC 4 I certify that this transcript 5 is a complete, true, and correct record of the 6 testimony of the deponent to the best of my ability 7 taken on Thursday, July 21, 2016. 8 I also certify that prior to 9 taking this deposition, the witness was duly sworn 10 by me to tell the truth. 11 I also certify that I am not a 12 relative or employee of a party, or a relative or 13 employee of an attorney for a party, have a contract 14 with a party, or am financially interested in the 15 action. 16 17 18 19 20	Page 159
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21 Cheryl McDowell, CSR-2662, RPR  
22 Notary Public, Livingston County  
State of Michigan  
23 Commission Expires September 13, 2019  
24